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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/462,845	01/13/2000	DAVID A. ESTELL	GC382-US	5579

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EXAMINER

PAK, YONG D

ART UNIT PAPER NUMBER

1652

DATE MAILED: 02/11/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/462,845

Applicant(s)

ESTELL, DAVID A.

Examiner

Yong Pak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,9-11,16,17 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,9-11,16,17 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

The amendment filed on November 26, 2002, canceling claims 2 and 18 and amending claims 1, 3, and 19, has been entered. This application is a 371 of PCT/FI99/00410.

Claims 1, 3-7, 9-11, 16-17 and 19 are pending.

Rejections and/or objections not reiterated from previous Office action are hereby withdrawn.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4-7, 11 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Murphy et al.

Murphy et al. (U.S. Patent No. 5,877,001) teach a *Bacillus* microorganism having a mutation or deletion of part of the gene encoding SP1 (Columns 15-22), resulting in a polypeptide with inactivated SP1 activity. The microorganism of Murphy et al. also is capable of expression heterologous proteins, such as the enzymes listed in claim 7. Murphy et al. also teach a method of producing heterologous proteins in a *Bacillus* microorganism (Columns 8-10 and claims 7-10). Therefore, the teachings of Murphy et al. anticipate claims 1, 4-7, 11 and 16.

Response to Arguments

Applicant's arguments filed November 26, 2002 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-7, 9-11, 16-17 and 19 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants argue that the specification describes how to produce mutated SP1 and that both the structure and function of mutant SP1s are described. The examiner disagrees. The specification does not contain any disclosure of the structure and function of all mutant SP1 genes resulting from mutation or deletion of part or all of the SP1 gene. The genus of DNA that comprise these above mutant and portions of SEQ ID NO:1 is a large variable genus with the potentiality of encoding many different proteins. Therefore, many structurally and functionally unrelated DNA are encompassed within the scope of these claims, including partial DNA sequences. The specification fails to describe any other representative species by any identifying characteristics or

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properties other than the "functionality" of encoding a polypeptide with an inactivated SP1 proteolytic activity and fails to provide any structure: function correlation present in all members of the claimed genus.

Claims 1, 3-7, 9-11, 16-17 and 19 remain rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for gram-positive microorganism having any mutation or deletion of part of all of SEQ ID NO:1 resulting in a mutant gene that inactivates SP1 proteolytic activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants argue that the specification is enabling because the specification teaches that residues in the catalytic domain may be deleted or mutated to inactivate the activity of the polypeptide. Applicants also argue that the specification teaches how to determine the activity of mutant SP1 enzymes. While these arguments are true, the claims encompass extremely large number of constructs broadly encompassed by the claims, such as partial DNA sequences. Therefore, the breadth of these claims is much larger than the scope enable by the specification.

Therefore, one of ordinary skill would require guidance in order to make gram-positive microorganisms having a mutation or deletion of part of all of the gene encoding

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SP1 (SEQ ID NO:1), wherein resulting mutation or deletion results in the inactivation of the SP1 proteolytic activity in a manner reasonable correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 8:00 A.M. to 4:30 P.M weekdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak
Patent Examiner

February 10, 2003



PONNATHAPU ACHUTAMURTHY
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